UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,498	03/16/2001	A. Bruno Frazier	6300.96.1	3953

22913 7590 02/26/2003

WORKMAN NYDEGGER & SEELEY
1000 EAGLE GATE TOWER
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UT 84111

EXAMINER
FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,498	FRAZIER ET AL.	
	Examiner	Art Unit	
	Kathryn Ferko	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-5, 8-19, 22-30, 33-37, 40-45, and 48-53 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Allen et al. in US Patent No. 6,334,856.

Regarding claims 1-5 and 8-19, Allen et al. disclose a microneedle array having a substrate with a substantially planar surface, as recited in column 4, lines 30-40; a plurality of hollow non-silicon microneedles on the planar surface of the substrate, each microneedle having a microchannel therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite end that extends beyond an edge of the substrate, as recited in column 4, lines 40-67, column 5, lines 1-38, and seen in the figures; microneedles each with a bottom wall, two side walls, and a top wall that define a microchannel, as recited in column 5; a bottom wall that is formed at least partially on top of the planar

surface of the substrate and the side walls and top wall are formed around a removable molding material, as recited in columns 9-15, especially column 9, lines 45-67, column 10, lines 42-67, column 15, lines 12-30, and seen in the figures; microneedles that are a two dimensional array, as recited in column 10, lines 43-57; microneedles that are a three dimensional array, as recited in column 21, lines 18-25 and column 22,lines 5-8; microneedles that are aligned substantially parallel to each other on the substrate, as seen in the figures; distal ends of each microneedle that extends beyond the edge of the substrate a distance from about 10um to about 100mm, as recited in column 5, lines 37-58 and column 9, lines 1-33; microchannels in each microneedle that has a cross-section area in the range from about 25um^2 to about 5000um^2, within the scope of that recited in column 5, lines 37-58 and column 9, lines 1-33; lengths of each microneedle that is from about 0.05um to about 5mm, and a width of each microneedle is that from about 0.05um to about 1mm, as recited in column 5, lines 49-57, column 8, lines 65-67, and column 9, lines 1-32; center-to-center spacing between individual microneedles that is from about 50um to about 200um, as recited in column 5, lines 48-52; a substrate the is a material selected from the group of glass, semiconductor material, metals, ceramics, plastics, and composites or combinations thereof, as recited in column 4, lines 32-40; microneedles that are composed of materials selected from the group of metals, plastics ceramics, glass, carbon black, and composites or combinations thereof, as recited in column 4, lines 40-58; microneedles that are composed of metal

materials selected from the group of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof, as recited in column 4, lines 40-58; microneedles that can withstand flow rates of up to about 1.5 cc/sec, as seen in column 24, Table 2; a coupling channel member that is composed of the same material as the microneedles, as seen in the figures; and a pair of structural support members that mechanically interconnect the microneedles and that precisely control penetration depth of the microneedles, as recited in column 8, lines 50-67.

With regard to claims, 22-30, Allen et al. disclose a microneedle array device having a plurality of hollow non-silicon microneedles having microchannels therethrough that provide communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite distal end; and at least one structural support member that interconnects the microneedles, as recited in column 4, lines 25-67, column 5, column 8 and seen in the figures. For depending claim rejections see corresponding rejection above.

Regarding claims 33-37 and 40-42, Allen et al. disclose a microneedle device having a substrate with a substantially planar surface; a hollow non-silicon microneedle on the planar surface of the substrate, the microneedle having at least one microchannel therethrough that provides communication between at least one input port at a proximal end of the microneedle and at least one output port at an opposite distal end that extends beyond an edge of the substrate, as

recited in column 4, lines 25-67, column 5, column 8, and seen in the figures; a structural support that is adapted to mechanically fix the microneedle to a surface that is penetrated by the microneedle as recited in column 8; and a plurality of microchannels, necessary for the array. For depending claim rejections see corresponding rejection above.

With regard to claims 43-45 and 89-50, Allen et al. disclose a microneedle having a hollow elongated shaft composed of a non-silicon material, the shaft defining at least one microchannel therethrough and having a proximal end and a distal end; at least one input port at the proximal end of the shank and at least one output port at the distal end, the microchannel providing communication between the at least one input port and the at least one output port, as recited in column 4, lines 25-67, column 5, column 8, and seen in the figures; a plurality of microchannels, necessary for the array; a structural support to control penetration depth, as recited in column 8; and a structural support that is adapted to mechanically fix the microneedle device to a surface that is penetrated by the elongated shaft, as recited in column 8. For depending claim rejections see corresponding rejection above.

Regarding claims 51-53, Allen et al. disclose a method of fabricating a microneedle via providing a substrate with a substantially planar surface; depositing a metal material on the planar surface to form one or more bottom walls for one or more microneedles; coating a top surface of one or more bottom walls with a photoresist layer to a height to correspond to a selected inner height

of a microchannel for the one or more microneedles; depositing a metal material to form side walls and a top wall upon the one or more bottom walls around the photoresist; removing the photoresist layer from the one or more channels; depositing via an electroplating process; and a metal that is selected from the group of palladium, titanium, chromium, gold, copper, and alloys thereof, as recited throughout the disclosure.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6-7, 20-21, 31-32, 38-39, and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in US Patent No. 6,334,856.

Allen et al. disclose the invention as claimed with the exception of explicitly reciting a three dimensional array that has a plurality of two dimensional arrays with spacers therebetween; a three dimensional array that is bonded together by a material selected from the group consisting of molding materials, polymeric adhesives, and combinations thereof; microneedles with a plurality of input ports; or microneedles with a plurality of output ports. On the other hand, given the disclosure of using a three dimensional array, it would be obvious to one with ordinary skill in the art to have a plurality of two dimensional arrays with spacers therebetween and a three dimensional array that is bonded together by

a material selected from the group consisting of molding materials, polymeric adhesives, and combinations thereof. When using arrays it is necessary to use spacers and adhesives are a common bonding method. Furthermore, having a plurality of input and output ports would also be obvious to one with ordinary skill in the art.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 3,964,482; US Patent No. 5,279,544; US Patent No. 5,611,806; US Patent No. 5,762,811; US Patent No. 5,928,207; US Patent No. 6,177,291; US Patent No. 6,256,533; US Patent No. 6,379,324; US Patent No. 6,397,466; US Patent No. 6,406,638; US Patent No. 6,511,463; WO 01/33614; WO 00/67647; WO 97/03718; and JP 3001-157715.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
February 19, 2003

Henry Bennett
Supervisory Patent Examiner
Group 3700